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Application No. 10/087,236
Amendment "D" dated January 9, 2006
Reply to Office Action mailed July 8, 2005

REMARKS

Claims 1 and 5-28 remain pending in the application. No claims have been amended, cancelled, or added by this amendment after final rejection. Reconsideration of the application is respectfully requested in light of the following arguments, the document attached to Amendment "D" as Exhibit A, and the Declaration of Harald Schmidt under 37 C.F.R. § 1.131 ("Schmidt Decl."), which was previously filed together with Amendment "D".

Applicants note that Amendment "D" and Response was erroneously characterized as a response after final rejection under Rule 116. In fact, the Office Action dated November 17, 2005 is a non-final rejection. The current amendment is being filed in order to remove issues under 35 U.S.C. § 112.

I. REQUEST FOR REJOINDER OF NON-ELECTED CLAIMS

The independent claims are all drawn to the elected invention of group I (*i.e.*, a two-component composition comprising a stiff thermoplastic biodegradable polymer and a soft thermoplastic biodegradable polymer), which included original claims 1-3, 7-12 and 14-25. Upon the allowance of the generic independent claims, Applicants respectfully request reconsideration and rejoinder of all remaining claims.

II. CLAIM REJECTIONS UNDER 35 U.S.C. § 112**A. Claim 5—Written Description**

The Office Action rejects claim 5 under 35 U.S.C. § 112, first paragraph, on the grounds that Applicants were not in possession of a composition in which "the stiff biodegradable polymer is included in an amount of at least about 55% by combined weight of the soft and stiff thermoplastic polymers". Office Action, p. 2 (emphasis added to show text quoted in Office Action). In response, Applicants have amended claim 5 to recite "greater than about 55%", which Applicants believe means the same thing as "at least about 55%" and which was found in claim 1 as originally filed. Moreover, the specification clearly teaches that the stiff biodegradable polymer may be included "preferably in a range from about 55% to about 98% by weight . . . (*i.e.*, the combined weight of the stiff and soft polymers)". Application, p. 9, ¶ [0020] (emphasis added). Applicants submit that claim 5 as amended fully meets the written description requirement of 35 U.S.C. § 112, first paragraph.

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B. Claim 1--Indefiniteness

The Office Action rejects claim 1 under 35 U.S.C. § 112, second paragraph, on the grounds that "the metes and bounds of 'substantially free' are indeterminate in scope". Office Action, p. 2. In response, Applicants first point to the favorable discussion in the MPEP regarding the use of the term "substantially". MPEP § 2173.05(b), (¶ D.) ("The court held that the limitation 'which produces substantially equal E and H plane illumination patterns' was definite because one of ordinary skill in the art would know what was meant by 'substantially equal.' *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988).").¹ When an application does not define what is meant by a "term of degree", "a determination is made as to whether one of ordinary skill in the art, in view of the prior art and the status of the art, would be nevertheless reasonably apprised of the scope of the invention". MPEP § 2173.05(b) (emphasis added). "The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph." *Id.*

For example, U.S. Patent No. 5,362,777 to Tomka, currently assigned to the same entity as the present application, recites a "thermoplastically processable starch" ("TPS") composition that is "substantially water free" and a method of manufacturing such composition. Tomka, col. 13, line 2; col. 14, line 40; Schmidt Decl., ¶ 7. The term "substantially water free" was successfully argued during prosecution to distinguish over a "destructured starch composition" containing 5-30% water described in the "Lay" reference. Schmidt Decl., ¶ 8. The fact that the USPTO issued claims 1 and 20 of Tomka over the Lay reference indicates that the term "substantially water free" was understood to mean some amount of water less than 5% so as to distinguish over the Lay reference. *Id.* This term was ultimately held to satisfy the definiteness requirement of 35 U.S.C. § 112, second paragraph. *Id.*

¹ Applicants performed a search of the USPTO patent database and found that since 1975 a total of 19,763 patents have been issued that employ the term "substantially free" in the claims, which is strong evidence that this term is *prima facie* definite since its use is so ubiquitous. Moreover, the USPTO database indicates that Examiner Ana Woodward has issued 6 patents that use the term "substantially free" in the claims.

For example, U.S. Patent Nos. 6,670,043 and 6,339,126 both employ the phrase "substantially free of carboxylic acid functionality" in the claims. U.S. Patent No. 6,429,266 uses the phrase "substantially free of water and substantially free of organic solvent" in the claims, while U.S. Patent No. 6,306,934 claims "an emulsion copolymer polymeric binder substantially free of volatile organic compounds". All four of these patents were examined and allowed by Examiner Ana Woodward.

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During litigation, the issue of the meaning of the term "substantially water free" was hotly contested. The trial court held this term to mean less than 5% water based on arguments made to distinguish over the Lay reference. *Biotec Biologische v. Biocorp*, 249 F.3d 1341, 1346 (Fed. Cir. 2001) (referring to the trial court's decision below). On appeal, the Federal Circuit confirmed this interpretation. *Id.* at 1347; Schmidt Decl., ¶ 9.

Applicants believe the phrase "substantially free of high boiling liquid plasticizers" is likewise definite and means that the optional thermoplastic starch component is either entirely free of high boiling liquid plasticizers or includes less than the amount required to form a thermoplastic starch melt in the absence of water. Schmidt Decl., ¶ 10. As is well-known to those of skill in the art of thermoplastic starch, the melting temperature of native starch approaches or exceeds the decomposition temperature of starch. *Id.* For that reason it is impossible to place native starch granules in a pan and cause them to melt in the absence of water or some other plasticizer. *Id.* Heating starch in the absence of a plasticizer will cause it to burn or decompose. *Id.*

In the 1980's, several attempts were made to manufacture "destructurized starch" ("DSS") using 5-30% water to form a thermoplastic starch melt, with the Lay reference of Warner-Lambert being among the most prominent DSS patents of the day. Schmidt Decl., ¶ 11. Because the melting point of starch exceeds the boiling point of water, destructurized starch can only be made using a closed vessel (e.g., a pressure cooker). *Id.* The tendency of water to vaporize during formation made the production of DSS difficult and economically non-viable. *Id.*

In an effort to avoid the negative effects of superheated and/or vaporizing water, Tomka taught that water (e.g., the natural water content of starch) could be replaced with one or more high boiling liquid plasticizers such as glycerin to lower the melting temperature of starch to below its decomposition temperature. Tomka; col. 13, lines 1-8; Schmidt Decl., ¶ 12. Such high boiling plasticizers solved the problem of the high volatility of water during processing because they have a vapor pressure of less than 1 bar at the melting temperature of the thermoplastic starch composition. Tomka, col. 13, lines 10-12; Schmidt Decl., ¶ 12. Tomka discloses and claims thermoplastic starch compositions in which the high boiling liquid plasticizer or "additive" is included in an amount of at least 5% by combined weight of the starch

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and additive, with 10-35% being preferred. Tomka, col. 6, lines 54-59; col. 13, lines 3-6; Tomka further teaches:

Depending on the properties desired for the shaped body to be produced, such as thermal and mechanical properties in particular, about 10 to 35% plasticizer or additive respectively is preferably added to the native starch, the water of the starch being replaced by the addition of the additives or removed by drying.

Id. at col. 6, lines 54-59 (emphasis added).

In view of the foregoing and the accompanying Schmidt Declaration, it is clear that starch cannot be melted in the absence of either at least 5% water, or at least 5% of a high boiling liquid plasticizer or "additive" in the absence of at least 5% water. Schmidt Decl., ¶ 14. The present application teaches that using high boiling liquid plasticizers such as glycerin may not be desirable in the case where a sheet or film is intended to contact food, since the plasticizer can diffuse out of the polymer matrix and into the food. Application, p. 9, ¶ [0023]; *see* Schmidt Decl., ¶ 14. Instead, the native starch granules are initially melted using water, which is then removed by evaporation, but only after the starch melt has been blended with one or more synthetic biodegradable polymers:

Preferred thermoplastic starch polymers for use in making food wraps may advantageously utilize the natural water content of native starch granules to initially break down the granular structure and melt the native starch. Thereafter, the melted starch can be blended with one or more synthetic biopolymers, and the mixture dried by venting, in order to yield a final polymer blend.

Application, pp. 9-10, ¶ [0023]; *see* pp. 33-34, ¶¶ [0092]-[0094]; Schmidt Decl., ¶ 15.

In view of the foregoing discussion and the accompanying Schmidt Declaration, the term "substantially free of high boiling liquid plasticizers" would be understood by one of skill in the art to mean less than the threshold amount of such plasticizers (*i.e.*, 5% by combined weight of starch and plasticizer) required to form a thermoplastic starch melt in the absence of at least 5% water. Schmidt Decl., ¶ 16. The same analysis would apply to claims 20, 23 and 25, which also employ the term "substantially free" in relation to a "high boiling liquid plasticizer" and/or "glycerin".

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C. Claims 5 and 7, line 2--Indefiniteness

The Office Action alleges that "it is unclear as to whether or not 'the stiff biodegradable polymer' would include any stiff natural starch component optionally present". Office Action, p. 2. The antecedent basis for the term "stiff biodegradable polymer" found in claims 5 and 7 is the phrase "stiff synthetic thermoplastic biodegradable polymer having a glass transition temperature greater than about 10° C." of claim 1. Claims 5 and 7 have therefore been amended to specify that a "stiff synthetic thermoplastic biodegradable polymer" is what is meant by the claims. As has been explained several times in previous responses, the term "synthetic thermoplastic biodegradable polymer" excludes natural polymers such as starch. Starch is described in the present application as a "natural" polymer. Application, p. 44, ¶ [0122]. Thus, the term "stiff synthetic thermoplastic biodegradable polymer" as used in claims 5 and 7 as amended excludes all forms of starch, including the optional thermoplastic starch component of claim 1.

D. Claims 5 and 7, lines 3-4--Indefiniteness

The Office Action alleges that "it is unclear as to whether or not the 'combined weight of the soft and stiff thermoplastic polymers' includes the optional natural starch component of claim 1." Office Action, p. 2. The same reasoning given above also applies here. The antecedent basis for the phrase "soft and stiff thermoplastic polymers" of claims 5 and 7 are the phrases "soft synthetic thermoplastic biodegradable polymer" and "stiff synthetic thermoplastic biodegradable polymer" of claim 1 (emphasis added). Thus, the phrase "soft and stiff thermoplastic polymers" has been amended to read "soft and stiff synthetic thermoplastic biodegradable polymers". Both phrases exclude starch, whether or not thermoplastic, such that the phrase "soft and stiff synthetic thermoplastic biodegradable polymers" of claims 5 and 7 as amended likewise excludes the optional thermoplastic starch component of claim 1.

E. Claims 8-12--Indefiniteness

The Office Action alleges that "it is unclear as to whether the recited glass transition temperatures pertain only to the corresponding 'synthetic' biodegradable polymers and not to any optional stiff or soft natural starch component." Office Action, p. 3. Again, the same reasoning discussed above applies here. The antecedent basis for the phrase "stiff biodegradable polymer" recited in claims 8-10 is the term "stiff synthetic thermoplastic biodegradable polymer" of claim 1 (emphasis). Likewise, the antecedent basis for the phrase "soft biodegradable polymer" of claims 11-12 is the phrase "soft synthetic thermoplastic biodegradable polymer" of

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claim 1 (emphasis). Claims 8-12 have accordingly been amended to recite either a soft or stiff "synthetic thermoplastic biodegradable polymer". Thus, the glass transition temperatures recited in claims 8-12 do not pertain to the optional thermoplastic starch component of claim 1.

F. Claims 25--Indefiniteness

The Office Action alleges that "it is unclear as to whether or not the optional thermoplastic starch is required to be stiff." Applicants respond that claim 25 is perfectly clear that the optional thermoplastic starch component of this claim is a "stiff biodegradable polymer having a glass transition temperature greater than about 10°C". Claim 25 states the following:

at least one stiff thermoplastic biodegradable polymer having a glass transition temperature greater than about 10° C., the at least one stiff thermoplastic biodegradable polymer optionally comprising thermoplastic starch that is substantially free of glycerin;

From the structure of the foregoing paragraph, it could not be plainer that it is the "at least one stiff thermoplastic biodegradable polymer", not the "at least one soft thermoplastic biodegradable polymer" that "optionally compris[es] thermoplastic starch that is substantially free of glycerin" (emphasis added).²

In view of the foregoing, Applicants submit that the claims fully satisfy the requirements of 35 U.S.C. § 112, first and second paragraphs.

III. CLAIM REJECTIONS UNDER 35 U.S.C. § 102/103

The Office Action rejects claims 1, 6, 8-12 and 25 under 35 U.S.C. § 102(b) as anticipated by or, in the alternative under 35 U.S.C. § 103(a) as obvious over, US 6,096,809 to Loreks et al. In making this rejection, the Office Action alleges that the term "substantially free of high boiling liquid plasticizers" or "glycerin" reads on the thermoplastic starch composition of Loreks et al. Office Action, p. 4. Applicants respectfully disagree and traverse this rejection. As discussed above, the term "substantially free of high boiling liquid plasticizers" would be understood by one of skill in the art to denote a composition that either includes no high boiling

² Moreover, there is no conflict between claim 25, on the one hand, and claim 28, which claims a "biodegradable composition comprising thermoplastic starch having sufficiently low crystallinity so as to be a soft thermoplastic polymer" in light of the further limitation in claim 28 that "the at least one stiff thermoplastic biodegradable polymer consist[s] essentially of one or more synthetic biodegradable polymers" (emphasis added). An example of thermoplastic starch having sufficiently low crystallinity as to constitute a soft thermoplastic polymer is TPS made using a plasticizer according to Tomka. Application, p. 33, ¶¶ [0092]-[0093].

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liquid plasticizer (e.g., glycerin) or an amount below the threshold amount (i.e., 5%) required to form a thermoplastic starch melt in the absence of at least 5% water. Schmidt Decl., ¶ 16.

Loreks et al., on the other hand, does not disclose thermoplastic starch manufactured in this manner. Instead, Loreks et al. discloses TPS that includes 10-40% of a high boiling liquid plasticizer:

Because of the poor suitability of native starch as an "engineering plastic" it is proposed according to the invention to use so-called thermoplastic starch, as is proposed, for example, in PCT/WO90/05161. This thermoplastic starch is obtained by processing native starch in the melt, by means of a plasticizing or swelling agent, to a homogeneous mass, where the proportion of swelling or plasticizing agent can as a rule amount to between 10 and about 40%, based on the overall weight of the mixture.

Loreks et al., col. 1, line 62 – col. 2, line 6 (emphasis added); Schmidt Decl., ¶ 17. Nor would it have been obvious in view of Loreks et al. to employ less than the threshold required amount of high boiling liquid plasticizer in view of the teaching that employing 10-40% of the plasticizer is necessary to overcome the problems relating to "the poor suitability of native starch as an 'engineering plastic'". Schmidt Decl., ¶¶ 18-19. Applicants therefore submit that the claims are novel and unobvious over Loreks et al., either alone or in combination with any other art of record for this reason alone. For example, dependent claims 5, 7, 14-19 and 26 are patentable over the combination of Loreks et al. and US 5,817,721 to Warzelhan et al., since Warzelhan et al. teaches nothing with respect to starch polymers of any kind, let alone the type recited in the claims at issue here.

The Office Action rejects claims 1, 5-12, 14-19, 25 and 26 under 35 U.S.C. § 103(a) as being unpatentable over US 5,883,199 to McCarthy et al. in view of Warzelhan et al. Because Warzelhan et al. is cited only with respect to the claims that include fillers, not in relation to the claimed polymer blends, Applicants will instead focus on the deficiencies of McCarthy et al. with respect to the claimed polymer blends. In making the rejection, the Office Action alleges that the "polyester polymer or copolymer" of McCarthy "embrac[es] aliphatic-aromatic copolyesters reading on the presently claimed soft polymer". In response, Applicants refer to the teachings of the present application and also the Schmidt Declaration in order to demonstrate that blends comprising a blend of a stiff thermoplastic polymer and the specific soft aliphatic-

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aromatic copolyesters recited in the claims (*i.e.*, having a glass transition temperature less than about 0°C or less than about -10°C) are neither taught nor suggested by McCarthy *et al.* *See* Schmidt Decl., ¶ 20.

McCarthy primarily discloses blends that include a blend of polylactic acid and homopolymers formed from one type of C₂-C₂₀ aliphatic diacid or copolymers formed using two or more C₂-C₂₀ aliphatic diacids. Col. 2, lines 21-35. Polymers and copolymers consisting entirely of one or more C₂-C₂₀ aliphatic diacids are purely aliphatic and therefore do not meet the limitation of claim 1, for example, that requires the use of an aliphatic-aromatic copolyester. The aliphatic polymers and copolymers of McCarthy are as "aliphatic" in nature and "non-aromatic" as is polycaprolactone ("PCL"). With respect to purely aliphatic polyesters, Applicants refer to the finding in the Office Action that the claimed "aliphatic-aromatic copolyester" is unobvious over the polycaprolactone (PCL) aliphatic polymers disclosed in U.S. 6,806,353 to Zhang *et al.* Office Action, p. 7. *See also* Schmidt Decl., ¶¶ 20-22 (describing the superior results obtained by using "soft" aliphatic-aromatic copolyesters such as ECOFLEX and EASTARBIO).

PCL is a polyester made by condensing together epsilon-caprolactone involving an initial ring opening reaction followed by condensing together the hydroxyacid formed in the ring opening. The aliphatic polyesters of McCarthy are virtually identical, except that they are made by condensing one or more C₂-C₂₀ aliphatic diacids with an aliphatic diol to form a purely aliphatic polymer. According to the present application, aliphatic-aromatic copolyesters (*e.g.*, ECOFLEX and EASTARBIO) are preferred over purely aliphatic polyesters. Moreover, Applicants refer to the Schmidt Declaration, which states that soft aliphatic-aromatic copolyesters such as ECOFLEX and EASTARBIO are superior over purely aliphatic polyesters due to their improved processability. Schmidt Decl., ¶ 20.

On the other hand, Applicants wish to point out that McCarthy does, in fact, teach an alternative embodiment in which the aliphatic polyester formed from one or more C₂-C₂₀ aliphatic diacids is copolymerized with up to 50% of an aromatic polyester. Col. 2, lines 42-44 (*i.e.*, "a copolyester of an aliphatic polyester and up to 50 percent, by weight, of an aromatic polyester"). McCarthy discloses two examples of copolyesters that include an aromatic polyester: (1) "polybutylene succinate-terephthalate (wherein the diacids of the polyester would be, for example, succinic acid, adipic acid, terephthalic acid, or any combination thereof)" and (2) a copolyester that includes up to 50% of "polyethylene terephthalate". Col. 2, lines 13-15;

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col. 6, lines 5-11. These are the only examples of polyesters that include an aromatic portion instead of being purely aliphatic. A review of these polymers reveals that McCarthy fails to teach or suggest a "soft" aliphatic-aromatic polymer. That is, McCarthy et al. fails to teach or suggest selecting an aliphatic-aromatic polyester having a glass transition temperature (Tg) that is less than 0°C, as recited in claim 25, or less than -10°C, as recited in claim 1, and then blending this polymer with a stiff polymer having a Tg greater than about 10°C. McCarthy et al. fails to suggest the desirability of blending an aliphatic-aromatic copolyester having a Tg less than 0°C (or -10°C), thus failing to provide one of skill in the art with the requisite motivation to obtain the claimed blends, shown to have superior results.

Applicants researched the Tg of both polyethylene succinate terephthalate and polyethylene terephthalate and found that they both have a glass transition temperature well above 0°C. For example, US Publication No. 2004/0247807 to Annan et al. suggests that the "polyethylene succinate terephthalate" as described in McCarthy has a Tg greater than 40°C. First, Annan et al. teaches that preferred aliphatic-aromatic copolyesters have a Tg greater than 40°C, preferably from 50°C to 110°C, and that "[t]he presence of aromatic groups increase the melting point (MP) and the glass transition temperature (Tg) of the resin." Annan et al., ¶ [0021]. In the next two paragraphs, Annan et al. discloses details regarding the preferred aliphatic-aromatic copolyesters, including "polybutylene terephthalate-co-adipate-co-succinate (50/45/5), wherein the parenthetical numbers represent the mole % of each acid reactant". Annan et al., ¶ [0023]. The terephthalate content of this polymer is therefore 50%. McCarthy teaches the desirability of using up to 50% aromatic polyester. Based on this, the preferred aromatic-containing polyesters of McCarthy will likely have a glass transition temperature greater than 40°C, making it a "stiff" rather than a "soft" aliphatic-aromatic copolyester, as required in both claim 1 and claim 25. Blends of "polyethylene succinate terephthalate" and PLA according to McCarthy contain two "stiff" polymers, as that term is defined, rather than a blend of a stiff and soft polymer, as required by claims 1 and 25.

The only other aromatic polyester disclosed in McCarthy is polyethylene terephthalate. Col. 6, lines 9-11. According to the document attached hereto at Exhibit A, polyethylene terephthalate has a Tg of 70°C, making it a "stiff" rather than a soft polymer. As discussed in Annan et al., a copolyester that contains 50% terephthalate groups has a Tg of at least 40°C. Accordingly, McCarthy does not inherently disclose blends that include a "soft" aliphatic-

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aromatic copolyester, such as ECOFLEX or EASTARBIO, which are quite different from and superior to "stiff" aliphatic-aromatic copolyesters because they yield blends having superior elongation and flexibility. See Schmidt Decl., ¶¶ 21-22. Nor does McCarthy et al. teach or suggest the desirability of specifically selecting an aliphatic-aromatic copolyester having a ratio of aliphatic and aromatic groups that results in a copolyester that is "soft" (i.e., that has a Tg less than about 0°C, as in claim 25, or less than -10°C, as in claim 1), and then blending that "soft" copolyester with a stiff polymer, as recited in claims 1 and 25. The blend in McCarthy comprising a polyethylene terephthalate copolymer and PLA contains two stiff polymers, rather than a blend of a stiff and soft polymer, as required by claims 1 and 25.

Because McCarthy is clearly silent with regard to the Tg of the aliphatic-aromatic copolyester, the only way the PTO could sustain a rejection of claims 1 and 25 over McCarthy is to provide evidence and/or technical reasoning establishing that the aliphatic-aromatic copolyesters of McCarthy "necessarily" have a Tg less than 0°C (claim 25) or less than -10°C (claim 1). MPEP § 2112 (inherency requires a showing that a claimed property or aspect is "necessarily" present, not merely "possibly", or even "probably"). No such evidence is contained in the Office Action. Nor does the Office Action even allege that the aromatic-containing copolyesters of McCarthy are "soft" biodegradable polymers having the claimed Tg. The Office Action therefore fails to satisfy the requirements articulated in MPEP § 2112 relating to the burden of proof for showing inherency. For this reason, the Office Action fails to articulate a *prima facie* rejection of claims 1 and 25 because it fails to show where each and every claim limitation is shown in the prior art, as required by MPEP 2143.

Notwithstanding the failure of the Office Action to establish that claims 1 and 25 are inherently *prima facie* obvious over McCarthy, Applicants have nevertheless brought forth rebuttal evidence showing that the aromatic-containing copolyesters disclosed in McCarthy are not "soft" polymers having a Tg of less than about 0°C (claim 25) or less than -10°C (claim 1), but rather "stiff" polymers because they apparently have a Tg greater than 40°C based on the teachings of Annan et al. and the document attached as Exhibit A. Accordingly, Applicants submit that claims 1 and 25 are unobvious over McCarthy et al., either alone or in combination with any other art of record (including Warzelhan et al.).

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IV. PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING

The Office Action provisionally rejects claims 1, 5-12, 14-19, 25 and 26 under the judicially created doctrine of obviousness-type double patenting relative to copending U.S. application Serial No. 11/103,999. Because the '999 application has only recently been examined, but has not yet been allowed, Applicant shall defer filing a Terminal Disclaimer at this time because there is no certainty that the '999 application will ever issue as a patent.

V. CONCLUSION

In view of the foregoing, Applicants believe that the claims as amended are in allowable form. In the event the Examiner finds any remaining impediment to the prompt allowance of the claims which may be overcome by Examiner Amendment, the Examiner is respectfully requested to initiate a telephonic interview with the undersigned attorney.

Dated this 9th day of January 2006.

Respectfully submitted,



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